[NIH Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; comment request

Opinions and Perspectives about the Current Blood Donation Policy for Men Who Have Sex with Men

SUMMARY: In compliance with the requirement of Section 3506(c) (2) (A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to the Office of Management and Budget (OMB) for review and approval.

PROPOSED COLLECTION: *Title:* Opinions and Perspectives about the Current Blood Donation Policy for Men Who Have Sex with Men. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The current policy for blood donation in the U.S. with respect to men who have sex with men (MSM) is that any man who discloses having had sex with another man since 1977 is deferred indefinitely from donating. However, data from donors who have tested disease marker positive and were interviewed regarding potential risk factors suggest that some individuals continue to donate blood without disclosing MSM activity in contravention of the policy. In the 1980s there were surveillance studies of risk factors among donors who were determined to be HIV positive in pre-donation testing: Results indicated MSM behavior to be a risk factor for 56% of male donors. In addition, as part of the Retrovirus Epidemiology Donor

Study (REDS), when anonymously surveyed by paper and pencil mailed surveys, 1.2% of male blood donors reported MSM behavior.

In a 2007 study conducted in Sweden, 19% of 334 MSM who responded to a survey that was included in a monthly publication targeted to the Lesbian, Gay, Bisexual and Transgender (LGBT) community reported donating blood at least one-time since 1985. The authors suggested that MSM donors may be motivated by perceived discrimination, particularly younger MSM.

Recent publications from the United Kingdom have reported what are likely the only population-based assessment of non-compliance with a similar restriction on blood donation for the MSM population as in the U.S.; this study was conducted in 2009 and 2010 and also estimated opinions about and self-reported intended compliance with the MSM deferral policy in place in the United Kingdom at that time. Note, the policy in the United Kingdom was modified in November 2011 and MSM in the United Kingdom are now allowed to donate if they have not been sexually active for a one-year period before donation.

Data similar to those collected in Sweden and the United Kingdom are not available for the U.S. Potential changes to the current MSM policy for blood donation requires additional data, including information about motivating factors and compliance with the current MSM policy or a modified policy in the MSM population and in current blood donors. Speculative analyses have been conducted but do not directly address important considerations related to this policy such as the current level of compliance (in the MSM population) and non-compliance (in the blood donor population). While many scientists and ethicists have expressed opinions in support or against modification of the

current MSM policy for blood donation, there is a lack of data that directly addresses important aspects of this policy debate. The proposed study will build off the studies conducted in Sweden and the United Kingdom and will collect directly relevant information on this topic by estimating the prevalence of compliance and non-compliance with the current MSM policy and assessing motivations for blood donation in the U.S. MSM population. Three research aims drive this study's protocols to provide valuable evidence on the motivations and compliance behaviors in the MSM and blood donor populations. The four geographic areas where the study will be conducted include the State of Connecticut, Western Pennsylvania, Southern Wisconsin, and the Bay Area of California.

The first aim seeks to assess opinions about and common themes within the MSM population with respect to blood donation and the current MSM policy. Specifically, within a population of self-identified MSM in the U.S., what common themes can be identified regarding knowledge and opinions of current blood donation eligibility, and would opinions, including self-reported intended compliance, improve if the current MSM policy were changed to a deferral of a defined shorter duration? Another objective is to use what is learned in the focus groups to help select proper venues for identifying MSM who might be interested in participating in a comprehensive survey to assess compliance and non-compliance with the current MSM policy (see second aim).

The second aim seeks to assess compliance and non-compliance in the MSM population with the current MSM blood donation policy by confidentially surveying two populations. One survey will be conducted in the MSM community to provide better estimates of compliance and non-compliance with the current policy and a second survey

will be conducted in male blood donors to evaluate how frequently men who have had sex with another man since 1977 are donating blood. The surveys will be conducted using an instrument that includes common content to maximize the comparability of the responses. Both surveys will be conducted using Internet-based techniques and currently available software (SurveyGizmo, www.surveygizmo.com).

The third aim seeks to assess motivations for donating in the group of self-identified MSM who are active blood donors in the U.S. Participants from the four geographic areas who report donating blood or the intention to donate will be asked to participate in confidential qualitative telephone interviews to identify their reasons for donating or wanting to donate blood.

Frequency of Response: Once. *Affected Public:* Individuals. *Type of Respondents:* Males 18 years old or older. The annual reporting burden is as follows: *Estimated Number of Respondents:* 4864; *Estimated Number of Responses per Respondent:* 1 per respondent for 4844 respondents and 2 per respondent for 20 respondents; *Average Burden of Hours per Response:* 1.5 hours for Aim 1, 0.33 hour for Aim 2, and 1.0 hour for Aim 3; and *Estimated Total Annual Burden Hours Requested:* 1,700. The annualized total cost to all respondents is estimated at: $13,600 (based on $8.00 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Study Aims	Estimated Annual Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours per Response	Estimated Total Annual Burden Hours Requested
Aim 1 – Focus Groups	64	1	1.5 hours	96
Aim 2.1 – Web	1,600	1	0.33 hours	528

interview				
Aim 2.2 – Web interview	3,200	1	0.33 hours	1056
Aim 3	20*	1	1 hour	20

*Aim 3 respondents are a subset of the respondents included in Aim 2

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and the assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Simone Glynn, MD, Project Officer/ICD Contact, Two Rockledge Center, Suite 9142, 6701 Rockledge Drive, Bethesda, MD 20892, or call 301- 435-0065, or E-mail your request to: glynnsa@nhlbi.nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: _February 9, 2012_____

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Keith Hoots,

Director, Division of Blood Diseases and Resources

National Heart, Lung, and Blood Institute, NIH

Dated: _February 13, 2012_____

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Lynn Susulske

NHLBI Project Clearance Liaison

National Institutes of Health

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